UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

JESSIE ACEVEDO, Plaintiff, v. JOHNSON & JOHNSON, and JANSSEN RESEARCH AND DEVELOPMENT, LLC, Defendants.	No. 16-CV-11977-DLC

MEMORANDUM AND ORDER

CABELL, U.S.M.J.

Plaintiff Jessie Acevedo has sued the manufacturers of the drug Risperdal after he took the drug and reportedly suffered serious side effects. The defendants, Johnson & Johnson ("J&J") and JANSSEN Research and Development ("Janssen"), moved to dismiss the complaint and the plaintiff subsequently moved to amend. (Dkt. Nos. 13, 29, 51). Those motions are now pending before the court. For the reasons explained below, the defendants' motions to dismiss will be granted and the plaintiff's motion to amend will be denied. However, the plaintiff will be permitted to attempt to re-plead two of his claims provided he can assert specific facts to show the claims are viable.

I. BACKGROUND

A. Facts as Stated in the Original Complaint

As alleged in the original complaint, the plaintiff is an inmate at the Old Colony Correctional Center in Bridgewater, Massachusetts. He at some point was prescribed Risperdal, an anti-psychotic drug. He subsequently developed breasts as a result of taking the drug and contends that the defendants failed to warn him of the drug's side effects. Complaint at pgs. 1-2.

B. Additional Facts as Stated in the Proposed Amended Complaint

The proposed amended complaint asserts additional facts and allegations. As alleged therein, J&J and Janssen developed and sold Risperdal. Amend. Compl. at ¶ 2. In or around 2007, Acevedo was prescribed Risperdal in connection with a diagnosed personality disorder. Id. at ¶ 4. Subsequently, Acevedo experienced weight gain, a decreased sex drive, tremors, and increased breast tissue, that is, gynecomastia. Id. at ¶ 6.

In or around May 2016, Acevedo saw a doctor regarding his mental health disorder and that doctor told him about Risperdal's side effects. The doctor told Acevedo that it was the defendants who informed the doctor of the drug's potential side effects. These disclosed side effects did not include gynecomastia. Id. at ¶ 9-10.

In 2016, Acevedo stopped taking Risperdal but the tremors and gynecomastia did not decrease. Id. at ¶ 13. As a result of his

gynecomastia, Acevedo was subject to taunting inside and outside of prison and suffered from severe depression, suicidal ideation and thoughts of self-mutilation. Id. at ¶ 17.

II. PROCEDURAL HISTORY

The plaintiff filed an original complaint on September 29, 2016, and J&J and Janssen moved to dismiss on January 31 and March 24, 2017, respectively.

The court subsequently issued an order to show cause when the plaintiff failed to respond and the plaintiff by letter dated May 31, 2017 informed the court that he wanted to prosecute his claims but was unsure how to proceed.

In June 2017 the court stayed the case in order to see if counsel could be obtained to assist the plaintiff. In the interim, on November 20, 2017, the plaintiff moved for leave to amend the complaint. On December 31, 2017, the defendants opposed the motion to amend.

On April 4, 2018, the court lifted the stay after efforts to obtain counsel for the plaintiff proved unsuccessful.

III. THE COMPLAINTS

A. The Original Complaint

The original complaint appears to assert two claims. It appears to allege that (1) the defendants negligently failed to warn the plaintiff of the side effects of Risperdal, and (2) the

plaintiff suffered emotional distress by virtue of the side effects he experienced.

B. The Proposed Amended Complaint

The proposed amended complaint is more fulsome and asserts five claims. First, it alleges that the defendants willfully and intentionally failed to inform medical providers and the plaintiff about the side effects of Risperdal, in violation of M.G.L. 106 § 2-318 and M.G.L. c. 93A § 2. Second, it alleges that the defendants' failure to notify medical providers of the possibility that Risperdal could cause gynecomastia constitutes negligence, fraudulent concealment and fraud. Third, it alleges that the defendants manufactured a defective product where they made a drug that caused gynecomastia and tremors. Fourth, it alleges that the defendants fraudulently concealed Risperdal's side effects when they sold it. Finally, it alleges that the plaintiff suffered emotional distress as a result of suffering side effects from taking Risperdal.

C. The Synthesized Claims

Comparing the two complaints, both allege that the defendants failed to warn others of Risperdal's side effects, and both assert claims for emotional distress. Further, Counts II and IV of the proposed amended complaint allege fraudulent concealment and are essentially duplicative. Synthesizing the two pleadings and

accounting for duplication, they appear to assert the following five claims, referred to here as counts for ease and clarity:

Count I alleges that the defendants violated M.G.L. c. 106, § 2-318 and M.G.L. c. 93A, § 2 by willfully and intentionally failing to inform medical providers and the plaintiff of Risperdal's side effects;

Count II alleges that the defendants negligently failed to warn the plaintiff of Risperdal's potential side effects;

Count III alleges that the defendants fraudulently concealed Risperdal's potential side effects from providers and the plaintiff;

Count IV alleges based on Risperdal's side effects that the defendants defectively manufactured it; and

Count V alleges that the defendants inflicted emotional distress upon the plaintiff.

IV. STANDARDS OF REVIEW

A. Motion to Amend

Under Fed. R. Civ. P. 15, a party may amend its pleading once as a matter of course within 21 days after serving it, or within 21 days after service of a responsive pleading or a motion filed under Fed. R. Civ. P. 12(b), (e), or (f). Fed. R. Civ. P. 15(a)(1). In all other cases, a party may amend a pleading only with written consent of the opposing party or leave of the court. Fed. R. Civ. P. 15(a)(2). "The court should freely find leave when justice so

requires." Id. "The leave sought should be granted unless the amendment would be futile or reward undue delay." *Abraham v. Woods Hole Oceanographic Inst.*, 553 F.3d 114, 117 (1st Cir. 2009). An amendment is considered futile if the proposed complaint would not survive a motion to dismiss. *See, e.g., Kemper Ins. Co. v. Federal Express Corp.*, 115 F. Supp. 2d 116, 125 (D. Mass. 2000).

B. Motion to Dismiss

On a motion to dismiss, the court "must assume the truth of all well-plead facts and give the plaintiff the benefit of all reasonable inferences therefrom." *Ruiz v. Bally Total Fitness Holding Corp.*, 496 F.3d 1, 5 (1st Cir. 2007). In order to survive a motion to dismiss, the complaint must state a claim that is plausible on its face. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). That is, "[f]actual allegations must be enough to raise a right to relief above the speculative level...on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id*. at 555.

In light of the applicable standards, the court focuses its inquiry on whether any of the five claims, which in the aggregate reflect the substance of the original complaint as well as the amended claims the plaintiff seeks leave to include, states a viable claim for relief.

V. ANALYSIS

The plaintiff contends that leave to amend should be granted because the proposed amended complaint helps to flesh out and clarify the plaintiff's specific claims. However, even accepting that the proposed amended complaint improves upon the original complaint, and even assuming *arguendo* that the plaintiff has not unduly delayed in seeking to amend, or that the amendment would not unduly prejudice the defendants, the court finds that none of the claims asserts a valid claim for relief. The court therefore will dismiss the original complaint and deny the motion for leave to amend. With respect to two claims, however, the court will give the plaintiff one additional opportunity to seek to cure deficiencies noted here.

A. Count I

Count I alleges that the defendants willfully and intentionally failed to inform the plaintiff or his medical providers of the potential risks associated with taking Risperdal, in violation of M.G.L. c. 106, § 2-318 and M.G.L. c. 93A, § 2. Count I fails to state a claim because neither of these statutes provides the plaintiff with a cause of action here.

First, M.G.L. c. 106, § 2-318 does not provide for an independent cause of action. The statute provides in pertinent part that a "[l]ack of privity between plaintiff and defendant shall be no defense in any action brought against the manufacturer,

seller, lessor or supplier of goods to recover damages for breach of warranty, express or implied, or for negligence…" M.G.L. c. 106, § 2-318. As the comments to the statute note, the purpose of this statute is to give entities other than a buyer the same benefits of any warranty the buyer received. See Id., Uniform Commercial Code Comment, No. 2 ("The purpose of this section is to give certain beneficiaries the benefit of the same warranty which the buyer received in the contract of sale, thereby freeing any such beneficiaries from any technical rules as to "privity."). The statute moreover is not germane to the present case because this is not a case where the defendants seek to escape liability for a breach of warranty or negligence claim on the ground that there was a lack of privity between the parties.

The second statute cited, M.G.L. c. 93A, § 2, does permit a plaintiff to bring an action for injury due to unfair or deceptive business practices, *Edlow v. RBW, LLC*, 688 F.3d 26, 39 (1st Cir. 2012), but the plaintiff cannot proceed under it here, for two reasons.

First, a plaintiff seeking to bring a Chapter 93A suit must first "submit a demand letter to defendants 30 days prior to filing a private action." *McKenna v. Wells Fargo, NA*, 693 F.3d 207, 217 (1st Cir. 2012). The demand letter, which is a prerequisite necessary to filing suit, must include a description of the unfair or deceptive act and identify the injured as the claimant.

Balsassari v. Public Finance Trust, 369 Mass. 33, 41 (2006). The plaintiff does not aver that he has supplied the defendants with a demand later and the defendants state explicitly that he has not. Second, even assuming the plaintiff were to do so, or has in fact done so, his 93A claim would still fail because a plaintiff seeking relief under Chapter 93A for an unfair or deceptive practice must show that he suffered an *economic* injury. *Tyler v. Michaels Stores, Inc.*, 464 Mass. 492, 501-02 (2013). By contrast, relief is not available where, as here, the plaintiff seeks redress for a physical injury. *See Rule v. Fort Dodge Animal Health, Inc*, 607 F.3d 250 (1st Cir. 2010)(affirming dismissal of 93A claim where manufacturer concealed risks of medicine at time of purchase but plaintiff did not suffer economic harm); *Donovan v. Philip Morris USA, Inc.*, 455 Mass. 215 (2009)(upholding 93A claim where ongoing risk of developing lung cancer required plaintiff to incur economic costs to cope with consequences of the risk). Count I therefore fails to state a valid claim for relief.

B. Count II

Count II asserts that the defendants were negligent for failing to notify medical providers that use of Risperdal could cause gynecomastia. In order to succeed on a claim of negligence, a plaintiff "must show (1) a legal duty owed by defendant to plaintiff; (2) a breach of that duty; (3) proximate or legal cause; and (4) actual damage or injury." *Jorgensen v. Mass. Port Auth.*,

905 F.2d 515, 522 (1st Cir. 1990). A plaintiff must moreover show that the manufacturer's failure to warn was the proximate cause of the plaintiff's injuries. *Calisi v. Abbott Labs, No. 11-10671-DJC,* 2013 WL 5441355, *15 (September 27, 2013). To establish that the manufacturer's failure to warn was the proximate cause of an injury, the plaintiff must show that "if additional warning had been given, it would have been heeded and a different result would have obtained." *Chamian v. Sharplan Lasers, Inc.*, No. 200000171, 2004 WL 2341569, *6-7 (Mass. Super. Ct. Sept. 24, 2004).

Notable here, Massachusetts has adopted the learned intermediary doctrine. Under this doctrine, prescription drug manufacturers only have the duty to warn prescribing physicians, rather than warning patients directly. *Liu v. Boehringer Ingelheim Pharmaceuticals, Inc.*, 230 F. Supp. 3d 3, 8 (D. Mass. 2017) (*citing Garside v. Osco Drug, Inc.*, 976 F.2d 77, 81 (1st Cir. 1992). The learned intermediary doctrine came about because "a patient's involvement in decision making concerning use of a prescription drug necessary to treat a malady is typically minimal or nonexistent." *Id*. (*citing MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass 131, 137 (1985)). Under this doctrine, the manufacturer's duty is fulfilled once it adequately warns the physician. *Garside v. Osco Drug, Inc.*, 976 F.2d, 77, 80 (1st Cir. 1992). Where the manufacturer fails to provide the physician with an adequate warning, the manufacturer may still be shielded from

liability if it can show that the prescribing physician would not have heeded an adequate warning." Id.

Applied here, Count II fails to assert a valid claim for relief because it fails to assert facts to show that the defendants failed to inform the plaintiff's physician regarding Risperdal's side effects. The amended complaint fails to identify the plaintiff's physician or to assert when s/he treated the plaintiff or what information, if any, the physician possessed regarding Risperdal. Without more, the claim is too vague and imprecise to provide meaningful guidance to the defendants. The court will therefore dismiss the complaint to the extent it alleges a negligent failure to warn, and will deny the motion for leave to amend to assert the claim as presently framed.

However, where the defendants' alleged failure to warn is in essence the plaintiff's core claim, the court will grant the plaintiff leave to try and re-plead Count II, subject to the plaintiff's ability to assert specific, non-conclusory facts demonstrating that the defendants failed to provide an adequate warning to the plaintiff's physician.

C. Count III

Count III alleges that the defendants knew that Risperdal could cause gynecomastia but fraudulently concealed its risks from medical providers and patients. Successful claims of fraudulent concealment "generally require [the] plaintiff to establish that

[the] defendant made a false representation which was knowingly 'false or was recklessly indifferent to its truth or falsity,' with the intention to defraud, upon which [the] plaintiff justifiably relied and incurred damages." *In re Neurontin Mktg.*, 618 F. Supp. 2d 96, 112 (D. Mass. 2009)(*citing Pinney v. Nokia*, Inc., 402 F.3d 430, 444 (4th Cir. 2005)). Additionally, the plaintiff must also plead and prove that the defendants took affirmative steps to conceal defects or to prevent the plaintiff from acquiring the knowledge of these defects. *Roadmaster Indus., Inc. v. Columbia Mfg. Co.*, 893 F.Supp. 1162, 1179 (D. Mass. 1995). A plaintiff, in addition to demonstrating there was an intentional concealment of information material to the transition, must also establish that the defendant owed the plaintiff a fiduciary duty or other similar relation of trust and confidence that required such disclosure. *See Bruno v. Bruno*, 10 Mass.App.Ct. 918, 919, (1980); *Walsh v. Chestnut Hill Bank & Trust Co.,* 414 Mass. 283, 288, n. 6, (1993).

The complaint here simply alleges in conclusory fashion that the defendants' failure to notify medical providers and patients of the risks of Risperdal while continuing to sell the drug constitutes fraudulent concealment. By contrast, the complaint does not assert any facts to show that the defendants knowingly took steps to conceal the drug's risks or to prevent the plaintiff or others from learning of them, or knowingly made a false

representation to the plaintiff's prescribing physician, or that the plaintiff relied on the false representation to his detriment.

In short, the plaintiff has not come close to meeting his burden to plead and prove that the defendants knowingly or recklessly made false statements regarding the risks of Risperdal for a fraudulent purpose. Count III therefore fails to state a valid claim for relief. And, as it is improbable the plaintiff could marshal the facts necessary to prove such a claim, leave to attempt to re-plead the claim will be denied.

D. Count IV

Count IV alleges a manufacturing defect because Risperdal has been associated with risks of tremors and gynecomastia. "A defect from manufacturing, as opposed to design, occurs when a product differs from identical products issued from the same manufacturer." *Waslow v. Glock, Inc.*, 975 F. Supp. 370, 377 (D. Mass. 1996). By contrast, a claim that "calls into question the entire product line...is properly construed as a design defect claim, not a manufacturing defect claim." *Booker v. Johnson*, 54 F. Supp. 3d 868, 876 (N.D. Ohio 2014). Here, the plaintiff has not alleged that the specific Risperdal he used was different from any other Risperdal the defendants made, but rather appears to allege that Risperdal is and was defective as designed. Accordingly, the court will presume that the complaint is heard to assert a claim of design defect.

When a product contains a design defect, "the product as designed is unreasonably dangerous for its ordinary purposes." *Laspesa v. Arrow International, Inc.*, No. 07-123370-NMG, 2009 WL 5217030, at 3 (D. Mass. Dec. 23, 2009). In order to prove a design defect, the plaintiff must show that the product was "made according to an unreasonably dangerous design and does not meet a consumer's reasonable expectation as to its safety." *Everett v. Bucky Warren*, Inc., 376 Mass. 280, 290 (1978) (internal quotations omitted). The focus of the claim must be on the design itself, not on the manufacturer's conduct, and it requires proof of the existence of a safer alternative design. *Id*. at 290-91; *see Evans v. Lorillard Tobacco Co.*, 465 Mass. 411, 428 (2013).

Here, the complaint alleges only that "the actions of the defendants in producing a drug that made the plaintiff have tremors and excessive breast tissue constitutes a manufacturing defect." There is by contrast no allegation that Risperdal was unreasonably dangerous as a product designed to treat a personality disorder and did not meet a consumer's reasonable expectation as to its safety. In the absence of facts sufficient to make such a showing, Count IV fails to state a valid claim for relief. It is improbable the plaintiff could marshal the facts necessary to prove such a claim and leave to try to re-plead the claim therefore will be denied.

E. Count V

Count V asserts a claim for emotional distress on the ground that Risperdal caused the plaintiff to grow female breasts, consider self-mutilation and suicide, and become depressed. It is not clear whether the plaintiff alleges negligent or intentional infliction of emotional distress.

To raise a claim of negligent infliction of emotional distress, a plaintiff must allege that (1) the defendant was negligent; (2) the plaintiff suffered emotional distress; (3) the emotional distress was caused by the defendant's negligence; (4) the plaintiff suffered physical harm manifested by objective symptomatology; and (5) a reasonable person would have suffered emotional distress under the same circumstances. *See Payton v. Abbott Labs*, 386 Mass. 540, 557 (1982). Here, the court finds that the complaint as presently framed fails to state a claim for negligent infliction of emotional distress because it does not adequately allege specific acts of negligence on the defendants' part. True, the plaintiff contends generally that he suffered side effects from the defendants' product but the fact that he suffered side effects does not conflate to a finding that the defendants were *a priori* negligent.

To the extent Count V alleges intentional infliction of emotional distress, the plaintiff in order to prevail must prove: "'(1) that the defendant intended to inflict emotional distress,

or knew or should have known that emotional distress was the likely result of his conduct,... (2) that the defendant's conduct was extreme and outrageous, beyond all possible bounds of decency and utterly intolerable in a civilized community, (3) the actions of the defendant were the cause of the plaintiff's distress, and (4) the emotional distress suffered by the plaintiff was severe and of such a nature that no reasonable person could be expected to endure it.'" *Heinrich ex rel. Heinrich v. Sweet*, 49 F. Supp. 2d 27, 39 (D. Mass. 1999)(*quoting Tetault v. Mahoney, Hawkes & Goldings*, 425 Mass. 456, 466 (1997)).

Here, the complaint fails to allege that the defendants either intended to inflict distress upon the plaintiff or knew or should have known that distress would result from their conduct. It also fails to allege sufficient facts to show that the defendants' conduct was extreme and outrageous, or that their conduct was the cause of the plaintiff's distress. Indeed, the complaint fails to allege that the defendants had any direct contact with the plaintiff or that any of their actions were specifically targeted at the plaintiff. Again, the fact that the plaintiff may have suffered serious side effects from Risperdal, while not to be trivialized, does not necessarily mean that the defendants intended the result or were responsible for his distress.

In short, Count V fails to state a valid claim for negligent or intentional infliction of emotional distress. However, to the

extent Count V is read to assert a claim for negligent infliction of emotional distress based on the defendants' failure to warn the plaintiff (via his physician) of Risperdal's side effects, that is the essence of Count II, which the court has given the plaintiff the opportunity to attempt to resurrect. Accordingly, the court will also permit the plaintiff to seek to re-plead Count V to that extent, understanding that the claim's viability will turn on the plaintiff's ability to assert specific facts showing that the defendants breached a duty which in turn caused the plaintiff to suffer harm.

VI. CONCLUSION

For the foregoing reasons:

1. Defendant Johnson & Johnson's motion to dismiss the original complaint (Dkt. No. 13) is **ALLOWED**;
2. Defendant JANSSEN Research and Development, LLC's motion to dismiss the original complaint (Dkt. No. 29) is **ALLOWED;**
3. Plaintiff Jessie Acevedo's motion for leave to amend the complaint (Dkt. No. 51) is **DENIED.** However, the denial is without prejudice as it relates to Counts II and V. As to those counts, the plaintiff shall be permitted one additional opportunity to seek leave within 30 days of the date of this Order to submit an amended complaint that

addresses the issues noted here, provided that he has a good faith basis for doing so.

SO ORDERED.

/s/ Donald L. Cabell
DONALD L. CABELL, U.S.M.J.

DATED: September 30, 2018